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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,927	08/01/2006	Rolf U. Halden	62589(71699)	3669

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EXAMINER	
SRIVASTAVA, KAILASH C	

ART UNIT	PAPER NUMBER
1657	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,927	HALDEN, ROLF U.	
	Examiner	Art Unit	
	Kailash C. Srivastava	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *1-10 and 23-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/01/006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The response filed 05 June 2009 to the Office Action mailed 10 April 2009 is acknowledged and entered.

Claims Status

2. Claims 1-49 are pending.

Restriction/Election

3. Election of Group II encompassing Claims 11-22 without traverse filed 05 June 2009 to the Office Action mailed 10 April 2009 is acknowledged and entered. . Since the election is made without traverse, the restriction requirement is deemed proper and is made FINAL.

Accordingly, Claims 1-10 and 23-49 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR §1.142(b) and MPEP § 821.03.

4. Claims 11-22 are examined on merits.

Information Disclosure Statement

5. The Information Disclosure Statement filed 01 August 2006 is acknowledged, entered, considered and duly initialed 1449 or equivalent is enclosed with the instant Office Action.

Claim Rejections - 35 USC §102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

> ***A person shall be entitled to a patent unless –***
>
> ***(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.***

7. Claims 11-13 are rejected under 35 U.S.C. §102(b) as anticipated by Scholin et al., (US Patent 6,187,530 B1, Applicants' IDS item AB).

Claims 11-13 recite a method to characterize cells in an environment, said method comprising the steps of collecting a sample through an automated device and subsequently processing the samples.

Regarding Claims 11-13, Scholin et al., teach a method and an aquatic autosampler device

to collect a biololgical sample, wherein said device is equipped with discrete samples of microorganisms at various locations and depths. The aquatic autosampler device moves a filter disk within a filter housing from a filter carousel into a filter housing holder. The filter housing holder, slidably mounted on a linear shuttle, moves the filter housing into a process position, where a syringe draws fluid in through a valve manifold and through the filter disk to collect samples on the filter disk. Reagents may then be passed over the filter disk to enable image-based identification and quantification of the cells on the filter disk. The filter housing may then be returned to the filter carousel for storage and further lab processing (Abstract, Lines 1-15). Please note the filter disk is absorbing the microorganisms through capillary action. Thus, each disk is considered to be an array of capillary microcosm wherein cells are trapped. Said disk is in a carousel (i.e., housing) that moves. Therefore one can collect microbial samples controllably. Furthermore, the disk can be stored and applied for laboratory processing, i.e., id retrieved from the environment and each disc constitutes at least one capillary microcosm to retrieve at least one sample, wherein said disk is analyzed for one cell characteristic of the cells through imaging. Furthermore, an automated sample handling device is applied for sampling and also for obtaining the sample and since the sample is passed through a disk for filtration is also concentrating the sample. Thus, Scholin et al., teach each and every step of the method instantly claimed in Claims 11-13.

Therefore, the reference is deemed to anticipate the cited claim.

Claim Rejections - 35 U.S.C. § 103

8. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> ***(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.***

9. Claims 11-18 and 21-22 are rejected under 35 U.S.C. §103 (a) as obvious over combined teachings from Schooling et al., (US Patent 6,187,530 B1, Applicants' IDS item AB) in view of Kosher et al. (US Patent 6,730,517 B1) and further in view of Iola et al (1997. MALDI-TOF Mass Spectrometric

Method for Detection of Hybridized DNA oligomers. Analytical Chemistry, Volume 73, Pages 2126-2131, Applicants' IDS, item CB).

Claims 11-18 and 21-22 recite a method to characterize cells in an environment, said method comprising the steps of collecting a sample through an automated device and subsequently processing the samples by subjecting them to mass spectrometry (i.e., MS) analysis, wherein MS is MALDI-TOF, and a cell lysate is analyzed for determining at least one molecular weight in comparison to a library of molecular weights for determining a turn-over rate of a particular isotopically labeled compound.

Regarding Claims 11-18 and 21-22, teachings from Scholin et al., have already been discussed at items 6-7 *supra*. Scholin et al., however, are silent regarding automated analysis through spectrometry of a biological sample and DNA fingerprinting via mass spectrometric (i.e., MALDI-TOF)method.

Koster et al., teach fully automated modular analytical systems with integrated instrumentation for analysis of biopolymer samples, such as nucleic acids, proteins, peptides and carbohydrates. Analytical methods of detection and analysis, such as mass spectrometry, radiolabeling, mass tags, chemical tags and fluorescence chemiluminescence, are integrated with robotic technology and automated chemical reaction systems to provide a high-throughput, accurate Automated Process Line (i.e., APL (Abstract, Lines 1-9). Koster et al., further teach methods for automated analysis of biopolymers using the integrated APL system. In preferred embodiments, provided are automated methods for preparing a biological sample for analysis; introducing the sample into an analytical instrument; recording sample data; automatically processing and interpreting the data; and storing the data in a bioinformatics database. In a particular embodiment, patient DNA samples are automatically analyzed to determine genotype (Column 2, Line 61 to Column 3, Line 2). Isola et al., teach MALDI-TOF mass spectrometry to measure the molecular weights of different DNA probes Total genonlic **DNA** of bacterio- phages bound to charge-modified nylon membranes **was** identified by the hybridization of species-specific oligo-nucleotide probes. Isola et al., further teach detection of hybridizations with multiple probes with MALDI-TOF mass spectrometry. Isola et al., also demonstrate that multiple-probe hybridization can be very sensitively resolved by mass spectrometry. **Six** probes different mass tag were used for hybridization on a spot. MALDI-TOF mass spectrometry was successfully used to measure these probes simultaneously (Abstract, Lines 14-22).

A person of ordinary skill in the art at the time the invention was made would have been motivated to combine teachings from Scholin et al., in view of Koster et al., and further in view of Isola

et al., to obtain a method to characterize cells in an environment , said method comprising the steps of collecting a sample through an automated device and subsequently processing the samples by subjecting them to mass spectrometry (i.e., MS) analysis, wherein MS is MALDI-TOF, and a cell lysate is analyzed for determining at least one molecular weight in comparison to a library of molecular weights for determining a turn-over rate of a particular isotopically labeled compound; because Koster et al., teach a method to analyze patient DNA samples in an integrated instrumentation for analysis of biopolymer samples, such as nucleic acids, proteins, peptides and carbohydrates employing analytical methods of detection and analysis, such as mass spectrometry, radiolabeling, mass tags, chemical tags and fluorescence chemiluminescence that are integrated with robotic technology and Soon et al., teach a method to Isola et al., teach MADI-TOF mass spectrometry to measure the molecular weights of different DNA probes. Thus, each of Koster et al., and Isola et al., remedy the deficiencies in teachings from Scholin et al., of automated analysis of biopolymer samples, such as nucleic acids, proteins, peptides and carbohydrates employing analytical methods of detection and analysis, such as mass spectrometry, radiolabeling, mass tags, chemical tags and fluorescence chemiluminescence and of applying MALDI-TOF to measure molecular weights. Please note hat measuring of DNA molecular weights and other techniques that Koster et al., teach would automatically give the turn over rate of a compound of interest.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine teachings from Scholin et al., in view of Koster et al., and further in view of Isola et al., to obtain a method to characterize cells in an environment , said method comprising the steps of collecting a sample through an automated device and subsequently processing the samples by subjecting them to mass spectrometry (i.e., MS) analysis, wherein MS is MALDI-TOF, and a cell lysate is analyzed for determining at least one molecular weight in comparison to a library of molecular weights for determining a turn-over rate of a particular isotopically labeled compound; because each of Koster et al., and Isola et al., remedy the deficiencies in teachings from Scholin et al., of automated analysis of biopolymer samples, such as nucleic acids, proteins, peptides and carbohydrates employing analytical methods of detection and analysis, such as mass spectrometry, radiolabeling, mass tags, chemical tags and fluorescence chemiluminescence and of applying MALDI-TOF to measure molecular weights..

From the teachings of the cited references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

10. No Claims are allowed for the aforementioned reasons. However, Claim 19-20 currently dependent on a rejected Claim (i.e., Claim 15) should be rewritten to overcome the rejection(s) under 35 U.S.C. §103(a) set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Upon resolution of the above-stated issues under 35 U.S.C. §103(a), further searching and/or consideration may be required.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kailash C Srivastava/
Examiner, Art Unit 1657

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12 September 2009
/David M. Naff/
Primary Examiner, Art Unit 1657